



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,880	05/03/2007	Joon-Haeng Rhee	Q95704	4676
23373 7590 05/13/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER ARCHIE, NINA	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 05/13/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No. 10/585,880	Applicant(s) RHEE ET AL.	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/7/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2010 has been entered.

Amendment Entry

2. The amendment filed April 7, 2010 has been entered. Claims 1 and 3-9 are pending. Claims 1, 3, and 7-8 are under examination. Claims 1, 3, and 8 have been amended. Claims 4-6 and 9 are withdrawn from consideration. Claim 2 has been cancelled.

Election/Restrictions

3. **The Amino Acid Election of Invention requirement for invention I (see pgs. 3-4 of the Office action mailed on 9/4/08) is hereby withdrawn and SEQ ID NOs: 2, 4, 6, 8, 10, and 12** are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Therefore SEQ ID NOs: **2, 4, 6, 8, 10, and 12** are under examination.

Information Disclosure Statement

4. The information disclosure statement filed on 4/7/2010 has been considered. An initialed copy is enclosed.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Therefore, the (foreign priority) date of 1/12/2004 is granted in the instant application.

Rejections Withdrawn

6. In view of the Applicant's amendment and remark following objections are withdrawn.

Art Unit: 1645

a) Rejection to claims 1-2 and 7-8 under 35 U.S.C. 102(b) as being anticipated by Adarem et al WO 2002/085933A1 Date October 31, 2002 has been withdrawn in view of applicants amendments.

Response to Arguments

7. Applicant's arguments with respect to claims 1-2 and 7-8 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by (Amaro et al Current Microbiology Vol. 25 (1992) pgs. 99-104).

The claims are drawn to mucosal vaccine adjuvant comprising isolated bacterial flagellins as an active component, wherein flagellins are originated from *Vibrio vulnificus* (claim 1), wherein said vaccine adjuvant is an adjuvant for vaccine selected from the group consisting of an anti-toxin vaccine; a live attenuated or killed vaccine; an anti-viral vaccine; an anti-cancer vaccine; an anti-sperm contraceptive vaccine, a recombinant protein, and peptide vaccine (claim 7), wherein the anti-toxin vaccine is against tetanus toxoid; the live attenuated or killed vaccine is against cholera and or typhoid fever; the anti-viral vaccine is against influenza and/or SARS; and the anti-cancer vaccine is against uterine cervical cancer (claim 8).

Amaro et al teach lipopolysaccharides isolated from *Vibrio vulnificus* strains obtained from whole cell lysates and outer membrane fragments for electrophoretic analysis (see pgs. 99-100). Amaro et al further teach antisera against *Vibrio vulnificus* was produced intravenously with said whole cell lysates (see pg. 100 column 2). Therefore the immunogenic lipopolysaccharides of *Vibrio vulnificus* strains isolated from whole cell lysates and outer

Art Unit: 1645

membrane fragments of Amaro et al necessarily encompasses isolated bacterial flagellins from *Vibrio vulnificus* which correlate to a mucosal vaccine adjuvant comprising isolated bacterial flagellins as an active component, wherein flagellins are originated from *Vibrio vulnificus*.

Independent claim 1 and dependent claims 7-8, recite the recitations, “wherein said vaccine adjuvant is an adjuvant for vaccine selected from the group consisting of an anti-toxin vaccine; a live attenuated or killed vaccine; an anti-viral vaccine; an anti-cancer vaccine; an anti-sperm contraceptive vaccine, a recombinant protein, and peptide vaccine (claim 7), wherein the anti-toxin vaccine is against tetanus toxoid; the live attenuated or killed vaccine is against cholera and or typhoid fever; the anti-viral vaccine is against influenza and/or SARS; and the anti-cancer vaccine is against uterine cervical cancer (claim 8). Given that Amaro et al teach said immunogenic lipopolysaccharides of *Vibrio vulnificus* encompasses isolated bacterial flagellins from *Vibrio vulnificus* necessarily possess the immunological and biological properties as that of the instant invention.

As to independent claim 1 and dependent claims 7-8 reciting the limitation, “a mucosal vaccine adjuvants” said recitation is considered an intended use and thus is given no patentable weight. Therefore the claims are drawn to a composition consisting essentially of isolated bacterial flagellins.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1, 3, 7-8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to independent claim 1, the claim is indefinite by reciting “A mucosal vaccine adjuvants”, the claim language is unclear because the claim states the mucosal vaccines adjuvants as plural adjuvants (i.e. two or more) but the article “A” indicates singular (i.e. one) mucosal vaccine. Appropriate correction required.

Art Unit: 1645

As to dependent claim 3, the claim is indefinite by reciting "one or more selected from the group consisting of the peptides", the claim language is unclear because in claim 3 independent claim 1 states "mucosal vaccine adjuvants" as plural adjuvants (i.e. two or more) indicating a mucosal vaccine adjuvants with two or more bacterial flagellins. Clarification in this regard is required.

Citation of Relevant Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kim et al Biochemical and Biophysical Research Communications 304 (2003) pgs. 405-410 teaches a *Vibrio vulnificus* flagellar hook-basal body flgBCDEFGHIJ operon with mutations in the flgC gene and administering bacteria comprising said hook-basal body flgBCDEFGHIJ operon which disclosed milder symptoms and signs of intragastric infection (see pgs. 406-408).

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/585,880

Page 6

Art Unit: 1645

Nina Archie

Examiner

Art Unit 1645

/Robert A. Zeman/

for Nina Archie, Examiner of Art Unit 1645